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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/576,094	05/22/2000	Miles A. Galin	A31632-A	2498

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EXAMINER	
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ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 09/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic -Action Summary	Application No.	Applicant(s)
	09/576,094	GALIN, MILES A.
	Examiner	Art Unit
	Urmi Chattopadhyay	3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6-11 and 21-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6-11 and 21-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 May 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Request for Continued Examination

1. The request filed on 1/29/04 for a Request for Continued Examination (RCE) under 37 CFR 1.114 based on Application No. 09/576,094 is acceptable and a RCE has been established. An action on the RCE follows.

Response to Amendment

2. The amendment filed 1/29/04 has been entered as Paper No. 18. The changes made to claim 1 have been approved by the examiner and new claims 21-40 have been added. All the pending claims, claims 1, 6-11 and 21-40, are being considered for further examination on the merits.

3. Applicant has added two independent claims that are broader in scope than claim 1. For clarity purposes, the prior art rejections set forth below are arranged to reject broadest independent claim 21 and claims dependent thereon first, less broad independent claim 33 and claims dependent thereon second, and least broad independent claim 1 and claims dependent thereon third.

Claim Objections

4. Claim 11 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the

claim(s) in independent form. Claim 1, on which claim 11 depends, already requires each haptic to be normal to the peripheral edge of the lens.

5. Claim 22 is objected to because of the following informalities: on line 2, "are" should be changed to --is--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1, 6-11 and 21-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

a) Claims 1, 21 and 33 all require that the concavely curved outer portion extend from the transition portion and that a first attachment point is defined at the juncture of the transition portion and the outer portion. These limitations constitute new matter because it appears from Figure 2 and page 14, lines 4-9 that the concavely curved outer portion (15) is extending from the intermediate beam (12) and not the transition portion, and that the first attachment point is defined at the juncture of the intermediate beam (12) and the outer portion (15). For examination purposes, the claims will be interpreted in light of Figure 2, wherein the concavely curved outer portion extends from the intermediate beam and defines a first attachment point at their juncture.

b) Claim 21 requires "at least one haptic" affixed to the lens, which means that the invention includes an embodiment wherein the ocular implant has only one haptic affixed to the lens. There is no support in the written specification or drawings for only one haptic, and it therefore, constitutes new matter.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1, 8-11 and 21-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kelman (USPN 4,828,558 as cited in applicant's IDS) in view of Schepel et al. (USPN 5,135,540).

Kelman discloses an intraocular lens with all the elements of claim 21, but is silent to the transition portion extending normal to the peripheral edge of the lens. See Figure 2 for an ocular implant (1) comprising an optic lens having an anterior surface, a posterior surface and a peripheral edge therebetween. See Figure 1 for at least one haptic (3, 4) affixed to the lens, wherein each haptic has a generally "S"-shaped configuration with a smooth transition portion extending to the peripheral edge of the lens (Figure 2), an intermediate beam extending from the transition portion, and a concavely curved outer portion extending from the intermediate beam to define a first attachment point at the juncture of the intermediate beam and outer portion, and a second attachment point at the distal end of the outer portion. Schepel et al. teaches an

intraocular lens wherein some material of the haptics is removed from the broad point of attachment to the lens so that the smooth transition portion of the haptic extends normal to the peripheral edge of the lens in order to permit greater movability of the haptics for flexure over the lens body. See Figure 2. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Schepel et al. to modify the IOL of Kelman by reducing the broad point of attachment of each haptic to the lens so that the transition portion extends normal to the peripheral edge of the lens in order to provide the haptic with greater movability for flexure over the lens body. This will facilitate their implantation through a small incision in the eye. See column 3, lines 31-45. In addition, this removal of material will provide the transition portion with a smooth concave curvature with a radius of curvature of less than 0.4mm (claims 30 and 31), which is shown in Figure 2.

Claims 22 and 23, see column 5, line 15 for both anterior and posterior surfaces being convex.

Claim 24, see column 5, lines 15-20 and column 7, line 28 for the convex structure and PMMA material (higher refractive index than surrounding medium) of the lens and concave structure of gas "layer" (lower refractive index) providing a positive optical power.

Claim 25, see column 7, lines 1-7 for the lens being foldable.

Claim 26, see column 5, lines 55-56 for the transition portion of each haptic having a thickness of *about* 0.2mm, which is broadly interpreted to fall within the required reduced thickness range.

With respect to claim 27, see Figure 1 for the intermediate beam length being slightly shorter than the optic diameter. Because the optic diameter is at most about 6 mm (column 5,

lines 44-45), the intermediate beam length will be *approximately* 5.25mm. The word *approximately* broadens the scope of the claim, and since the specification does not define the metes and bounds of "approximately 5.25mm", Examiner is broadly interpreting it.

With respect to claims 28, 29 and 32, because the haptics meet all the structural limitations and configuration requirements with respect to the optic lens, the ocular implant will have a vault, saggita value and omega value within the required ranges.

Claim 33, see rejection to claims 21, 22 and 24 supra and column 4, lines 4 for an anterior chamber ocular implant. With respect to the limitation of "for placement in the anterior chamber of a phakic eye", a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. Because the IOL of Kelman and Schepel et al. is capable of performing the intended use, being used in the anterior chamber of a phakic eye, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Claims 34 and 35, see rejections to claims 26 and 27, supra.

Claims 36, 37 and 40, see rejections to claims 28, 29 and 30, supra.

Claims 38 and 39, see rejections to claims 30 and 31, supra.

Claim 1, see rejection to claims 33-35, supra. The two haptics (3, 4) provide a four-point attachment. Because the IOL of Kelman and Schepel et al. have all the required structural limitations of applicant's claimed invention, if it were to be placed in the anterior chamber of a

phakic eye, which it is certainly capable of being, contact of the lens with other anatomic bodies would be avoided, as would contact of the haptics with the iris and corneal endothelium.

Claim 8, see column 7, lines 27-29 for lens being fabricated from PMMA.

Claims 9 and 10, see column 7, lines 36-48.

Claim 11, see rejection to claim 1, supra.

10. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kelman and Schepel et al., as applied to claim 1 above, and further in view of Li et al. (USPN 6,132,462 as cited in previous office action).

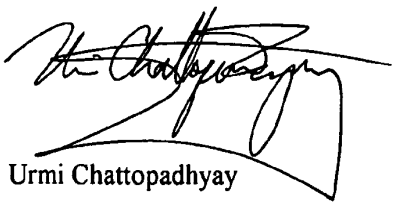
Kelman, as modified by Schepel et al., discloses an intraocular lens with all the limitations of claim 1, but is silent to the additional limitation of the implant being coated with a specific sulfated polysaccharide medicament, as required by claims 6 and 7. Li et al. teaches a copolymer intraocular lens coated with heparin in order to raise biocompatibility and prevent deposition of cells. See column 6, lines 19-29. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Li et al. to modify the intraocular lens of Kelman, as modified by Schepel et al., by including the specific coating in order to raise biocompatibility and prevent deposition of cells.

Response to Arguments

11. Applicant's arguments with respect to claims 1 and 6-11 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Urmi Chattopadhyay whose telephone number is (703) 308-8510 and whose work schedule is Monday-Friday, 9:00am – 6:30pm with every other Friday off. The examiner's supervisor, Corrine McDermott, may be reached at (703) 308-2111. The group receptionist may be reached at (703) 308-0858.

Should the applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 872-9306. Should applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.



Urmi Chattopadhyay

Art Unit 3738